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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/597,580	06/20/2000	Gary L. Griffiths	018733/0987	5842

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FOLEY AND LARDNER
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER	
JONES, DAMERON LEVEST	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 02/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/597,580	GRIFFITHS ET AL.	
	Examiner	Art Unit	
	D. L. Jones	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42,44 and 46-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-42,44 and 46-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

ACKNOWLEDGMENTS

1. The Examiner acknowledges the amendment filed 11/3/03 wherein claims 1, 21, 38, and 53 were amended and claims 43 and 45 were canceled.

Note: Claims 1-42, 44, and 46-54 are pending.

RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS

2. The Applicant's arguments filed 11/3/03 to the rejection of claims 1-16, 18, 20-42, 44, 46, and 50-54 made by the Examiner under 35 USC 103 and/or 112 have been fully considered and deemed persuasive for reasons of record. Therefore, the said rejections are hereby withdrawn.

NEW GROUNDS OF REJECTIONS

112 First Paragraph Rejections

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-42, 44, and 46-54 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for an infectious disease agent in a patient. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are (1) nature of the invention; (2) state of the prior art; (3) level of one of ordinary skill in the art; (4) level of predictability in the art; (5) amount of direction and guidance provided by the inventor; (6) existence of working examples; (7) breadth of claims; and (8) quantity of experimentation needed to make or use the invention based on the content of the disclosure.

(1) Nature of the invention

The claims are directed to a composition having a targeting moiety that binds to a tumor or infectious disease-causing agent.

(2) State of the prior art

The prior art of record do not indicate which specific infectious disease agents or class of agents that are useful with the claimed invention.

(3) Level of one of ordinary skill in the art

The level of one of ordinary skill in the art is high. Independent claims 1, 37, and 38 encompass a vast number of possible infectious disease causing agents. Applicant's specification does not enable the public to make or use such a vast number of possible agents in combination with the compositions being claimed.

(4) Level of predictability in the art

The art pertaining to compositions having infectious disease causing agents as set forth in independent claims 1, 37, and 38 is highly unpredictable. Determining the various types of agents or class of agents that will associated with Applicant's marker substance requires various experimental procedures and without guidance that is applicable to all compositions as set forth by Applicant's claims, there would be little predictability in performing the claimed invention.

(5) Amount of direction and guidance provided by the inventor

Independent claims 1, 37, and 38 encompass a vast number of agents. Applicant's limited guidance does not enable the public to prepare the infectious disease causing agents. There is no directional guidance for the agents or specific characteristics/properties that will result in agents useful with the instant invention. Hence, there is no enablement for infectious disease causing agents.

(6) Existence of working examples

Independent claims 1, 37, and 38 encompass a vast number of infectious disease causing agents. Applicant's working examples do not enable the public to prepare or use such agents. While Applicant's claims encompass a plethora of possible infectious disease causing agents, the specification, page 3, lines 2-3, states that the infectious diseases include bacterial, viral, and fungal diseases, but do not provide any further explanation or an example of the infectious causing agents thereof.

(7) Breadth of claims

The claims are extremely broad due to the vast number of possible infectious disease causing agents known to exist.

(8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure

The specification does not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with the claims. In particular, the specification fails to enable the skilled artisan to practice the invention without undue experimentation. Furthermore, based on the unpredictable nature of the invention, the state of the prior art, and the extreme breadth of the claims, one skilled in the art could not perform the claimed invention without undue experimentation.

112 Second Paragraph Rejections

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 1-42, 44, and 46-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 38, lines 13-14: the claim as written is ambiguous because of the phrase '(c) corresponding enzymes and prodrug substrates'. In particular, it is unclear what enzymes and substrates Applicant is referring to. Pleas clarify in order that one may readily ascertain what is being claimed.

Claims 1-42, 44, and 46-54: the claims as written are ambiguous because one cannot readily ascertain what is being claimed. Specifically, the claims as written read on an infectious disease. However, one of ordinary skill in the art would not be able to

ascertain what is infectious disease(s) are encompassed in the claim as written. Applicant is respectfully requested to clarify the claim in order that one may determine what is being claimed.

Double Patenting Rejections

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1, 25, and 26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 25 of U.S. Patent No. 5,736,119. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions are directed to compositions comprising an avidin/biotin and therapeutic/detection agent.

9. Claims 37-40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 25 and 29-34 of U.S. Patent No. 5,846,741. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions are directed to compositions comprising a boron complex (therapeutic agent) and a binding pair.

10. Claims 1, 25, and 27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 41 of U.S. Patent No. 5,482,698. Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions are directed to compositions comprising a multivalent target-polymer complex.

11. Claims 1-42, 44, and 46-54 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 46, 52, 54-66, 69-95, 104, 108-127, 129, 134-153, 158, 164-166, 169, 204, 206, and 210 of copending Application No. 10/361,026. Although the conflicting claims are not identical,

they are not patentably distinct from each other because both inventions are directed to compositions encompassed by independent claims 1, 37, and 38 of the instant invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

COMMENTS/NOTES

12. It should be noted that no prior art has been cited against Applicant's claims; however, Applicant must address and overcome the double patenting rejections. The claims are distinguished over the prior art of record because the prior art neither anticipates nor renders obvious compositions as set forth in independent claims 1, 37, and 38. The closest art is Applicant's own work over which double patenting rejections have been made.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

D. L. Jones
Primary Examiner
Art Unit 1616

February 9, 2004